IN THE UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS
EASTERN DIVISION

GERALD SYLVIA and CYNTHIA ROSE, h/w	)	
	)	**COURT FILE NO._____**
Plaintiffs,	)	
v.	)	
GENENTECH, INC.; XOMA (US) LLC; XOMA, LTD; DOE DEFENDANTS 1 THROUGH 10,	)	**COMPLAINT FOR DAMAGES AND DEMAND FOR JURY TRIAL**
Defendants.	)	

NOW COME, Plaintiffs, Gerald Sylvia and Cynthia Rose, by and through their counsel, Pogust Braslow & Millrood, LLC and, and for their cause of action, sues the Defendants and alleges as follows:

STATEMENT OF CASE

1. The Defendants, Genentech and Xoma, the manufacturers of Raptiva, were aware of the dangers associated with Raptiva before their biologic was introduced to the market. The manufacturers failed to warn the Plaintiff, Gerald Sylvia, or his physician, of Raptiva's effects on the immune system. The Defendants knowingly and recklessly left the defective product on the market to be given to unsuspecting patients when safer alternatives were available. Because of the Plaintiff's exposure to Raptiva, he developed meningitis and acute retinal necrosis, and has sustained permanent, disabling, and horrific injuries including the loss of vision in his right eye.

2. Raptiva was used for the treatment of mild to severe plaque psoriasis in adults who are candidates for systemic therapy or phototherapy to control their psoriasis.

3. Raptiva works by suppressing the patient's immune system to reduce psoriasis flare-ups but increases the risk of opportunistic infections such as bacterial sepsis, viral meningitis, invasive fungal disease and progressive multifocal leukoencephalopathy.

THE PARTIES

4. Plaintiffs, Gerald Sylvia and Cynthia Rose are husband and wife, and residents of the Commonwealth of Massachusetts, residing at 9 Millstone Street in North Falmouth.

5. Defendant Genentech, Inc. ("Genentech") is a Delaware corporation with its principal place of business in South San Francisco, California. At all times herein mentioned, Genentech designed, developed, manufactured, tested, analyzed distributed, recommended, merchandised, advertised, promoted, supplied and sold to distributors, and retailers for resale to physicians, hospitals, medical practitioners and the general public, a certain pharmaceutical product, hereinafter referred to as Raptiva; nationwide and in the Commonwealth of Massachusetts.

6. Defendant Xoma (US) LLC is a Delaware corporation with its principal place of business in Berkeley, California, and is wholly owned subsidiary of defendant Xoma, LTD., a business entity formed under the laws of Bermuda with its principal place of business in Berkeley, California (collectively referred to herein as "Xoma"). Xoma researches, develops and manufactures antibody and other protein-based biopharmaceuticals for disease target that include immunological and inflammatory disorders. At all times herein mentioned, Xoma was engaged

in the research, design, development, clinical testing and productions of Raptiva in collaboration with Genentech.

6. The collaboration agreement between Xoma and Genentech for Raptiva provided Xoma to share in the profits generated from Raptiva based on sales and provided for marketing costs to be shared between Defendants.

7. The true names and capacities, whether individual, corporate, partnership, associate or otherwise, of Defendant Does 1 through 10, inclusive (hereinafter "DOE DEFENDANTS"), are presently unknown to Plaintiffs who therefore sue these DOE Defendants by fictitious names. Plaintiffs are informed and believe and thereupon allege that each of the fictitiously named Doe Defendants are responsible in some manner for the occurrences alleged herein and Plaintiffs' damages were proximately caused by such Doe Defendants' acts and omissions. Each reference in this Complaint to "Defendants" or a specifically named Doe Defendant shall also refer to all Doe Defendants sued under fictitious names. Plaintiffs will amend this Complaint to assert true names and capacities of fictitiously named Doe Defendants when such has been ascertained.

10. At all times herein relevant to this Complaint, each of the aforementioned Defendants were the agents, employees associates, partners, joint ventures, shareholders, owners, or representatives for each other in engaging in acts alleged herein, and were, at all times, acting within the purpose and scope of such agency and with the consent and approval of said Defendants.

JURISDICTION AND VENUE

11. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §1332 because there is complete diversity of citizenship between the parties and the amount in controversy exceeds $75,000.00 exclusive of interest and costs. Plaintiffs are residents and citizens of Massachusetts, and none of the Defendants have their headquarters or principal places of business in Massachusetts.

12. Venue in this district is appropriate under 28 U.S.C. § 1391 because all Defendants do business in this district, are subject to personal jurisdiction in this district, and Plaintiff suffered injury as a result of Defendants' conduct in this district.

13. The Defendants now, and at all times mentioned in this Complaint, conducted business and solicited business in the Commonwealth of Massachusetts through the sale of Raptiva and/or other healthcare products to hospitals, businesses, institutions, distributors, and individuals in this state.

15. Upon information and belief, relevant facts exist in this case applicable to the laws of Massachusetts. Plaintiffs reserve the right to pursue the applicable legal claims and remedies available to them under the appropriate choice of law, including but not limited to Section 2, Chapter 93A of the Massachusetts General Laws regarding unfair or deceptive acts.

STATEMENT OF FACTS

A. *CASE SPECIFIC FACTS*

16. Plaintiff Gerald Sylvia, suffered from chronic plaque psoriasis.

17. In April 2004, Plaintiff's dermatologist recommended weekly injections with Raptiva.

18. At no time prior to beginning treatment or during treatment was Plaintiff ever warned of risks associated with these weekly injections.

19. Plaintiff continued the regime of self-administered weekly Raptiva injections until on or about January 11, 2008, when he was admitted to the hospital after several days of continuous and sharp headaches, with no relief from prescribed medications.

20. Plaintiff was diagnosed with meningitis and started on an antibiotic.

21. On or about January 25, 2008, Plaintiff developed foggy vision in his right eye and was ultimately diagnosed with acute retinal necrosis.

22. On July 30, 2008, due to the acute retinal necrosis in the right eye, which caused a host of problems including widespread retinal scarring and retinal detachment, Plaintiff underwent surgery in order to save his right eye.

23. Since his eye surgery, Plaintiff is only able to see grayness from his right eye and is legally blind.

24. As a further direct and proximate cause of Plaintiff's loss of visions, he will suffer the loss of his employment as a Steamship Hand for the Coast Guard due to the vision requirements of that position.

B. *GENERAL FACTS*

26. Psoriasis is a chronic, non-contagious, non-life threatening, autoimmune disease which affects the skin. Plaque psoriasis, the most common form of the disease, is characterized by inflamed patches of skin ("lesions") topped with slivery white scales.

27. Conventional psoriasis treatment consists of topical agents, ultraviolet therapy, cyclosporine, and methotrexate.

28. In the past decade, there have been considerable advances in the understanding of pathogenesis of psoriasis. It is now recognized that the aberrant activation and migration of T-cells into the skin is central to the disease. A T-cell is a type of white blood cell and the cell the body uses to fight infection.

29. Raptiva is administered by injection, and belongs to new class of drugs known as biologics. The term "biologics" is used to describe medications that are produced by means of biological processes involving recombinant DNA technology. These medications are usually classified into one of three types: (1) substances that are (nearly) identical to the body's own key signaling proteins such as growth-stimulating hormone; (2) monoclonal antibodies (that are similar to the antibodies that the human immune system uses to fight off bacteria and viruses) are "custom-designed" and can therefore be made specifically to counteract or block any given substance in the body, or to target any specific cell type; and, (3) receptor constructs (fusion proteins), usually based on a naturally-occurring receptor linked to the immunoglobulin frame.

30. Raptiva is a recombinant humanized monoclonal antibody that binds to human CD11a, one of the two components which form lymphocyte function-associated antigen 1(LFA-1). LFA-

1 is an important molecule in lymphocyte adhesion, activation, and migration of tissues. It is involved in the recruitment of inflammatory cells to the site of infection. The skin lesions that occur in psoriasis are caused by the actions of T-cells that are attracted to the site of inflammation. LFA-1 is found on all T-cells, and also on B-cells, macrophages and neutrophils.

31. Raptiva was designed to inhibit the function of the T-cell by interfering with the ability of the LFA—1 to bind to the endothelium adhesion molecule ICAM-1 and migrate from the blood into the skin where it would promote an inflammatory response and the growth of skin lesions.

32. Raptiva's prevention of adhesion of LFA-1 (i) diminishes T-cell adhesion to the lining of blood vessels; (ii) decreases the migration of T-cells to sites of inflammation; (iii) reduces the potential of T-cells to kill malignant cells, and, (iv) contributes to the inhibition of activation of T-lymphocytes which are needed to fight infection.

33. It is generally accepted in the medical community that suppression of T-cell function predisposes the body to serious life-threatening infections (encephalitis, meningitis, and progressive multifocal leukoencephalopathy (PML)), neurological complications, and the development of lymphoma, malignancies and possibly death.

34. It is generally accepted in the medical community that prolonged inhibition of LFA-1 would impair the body's defenses against infection resulting in increased risk of infection, malignancy, lymphoma and death.

35. It is generally accepted in the medical community that the role of LFA-1 and its relationship to the body's immune system was well known long before Raptiva was approved in October 2003 for use in the management of patients with psoriasis.

C. *XOMA AND GENETECH'S RACE FOR FDA APPROVAL OF RAPTIVA*

36. Raptiva was researched, developed, clinically tested, manufactured, advertised, marketed, promoted and sold by Xoma and Genentech.

37. In April 1996, Xoma, entered into a collaboration agreement with Genentech for the development of Raptiva. Under the terms of the agreement, Xoma was responsible for the scale-up and development of Raptiva, and bringing it through Phase II clinical trials. Upon meeting certain milestones, Xoma would have an option to participate in the development through U.S. approval, after which they would earn the right to co-promote and share in the profits in the United States and receive royalties on sales elsewhere. Pursuant to the agreement, Genentech purchased 1.5 million shares of Xoma stock and funded Xoma's research, design, development and testing costs for Raptiva through 1998.

38. In September 1996, Xoma filed an Investigational New Drug application (IND) with the U.S. Food and Drug Administration (FDA) for clinical testing of Raptiva in patients with moderate to severe patients.

39. In 1998, Xoma met the original collaboration agreement milestones by successful completion of a Phase II trial and Genentech made a $2 million milestone payment to Xoma.

40. Raptiva was important to the future of Xoma. In its twenty years, Xoma had never turned a profit and if approved, Raptiva would be Xoma's first attempt at a commercial product which in turn would generate much needed revenue for the company. For that reason, Defendants invested in the cross development of Raptiva for uses in other highly profitable disease markets, namely rheumatoid and psoriatic arthritis.

41. In December 1999, Genentech and Xoma announced initiation of Phase III Clinical Trials for Raptiva. Defendants intended to file a biologics license application (BLA) with the FDA by the end of 2001 in order to compete with rivals drugs, Biogen's Amevive and Immunex Corp./Wyeth's Enbrel in the lucrative psoriasis market. Raptiva was expected to reach peak annual sales of $400 million if approved.

42. During Phase III testing, Defendants decided to relocate the Raptiva manufacturing facilities from Xoma to Genentech in order to allow for production of large-scale commercial quantities of Raptiva. This resulted in the source material achieving a higher serum concentration than the Xoma material. The FDA asked Genentech to conduct a study of the "new" Raptiva in psoriasis patients due to the difference in the Raptiva serum concentration that was previously tested in patients. This delayed Raptiva's approval for filing with the FDA and significantly eroded Raptiva's sales potential behind its competitors.

43. On December 27, 2002, Genentech submitted Raptiva Biologic License Application to the FDA's Center for Biologics Evaluation and Research (STN BL 125075/0).

44. In January 2003, the FDA approved the marketing of Biogen's Amevive for the treatment of psoriasis, one of Defendants' main competitors in the biologics psoriasis market. At the time, the competition to develop a treatment for psoriasis was intense. The first company to get its drug to market would gain a substantial first-mover advantage over companies entering the market later.

45. On March 31, 2003, Xoma and Genentech entered into an amended collaboration agreement which set forth the terms and conditions relating to all aspects of its ongoing

development and marketing of Raptiva. Under the terms of the amended collaboration agreement, Defendants agreed to establish a Joint Steering Committee ("JSC") to oversee and manage the collaboration in the Co-Promotion Territory (the United States).

46. Under the terms of the 2003 amended collaboration agreement, Genentech was responsible for the transfer of all preclinical data, assays, and associated materials, protocols, procedures and any other information in Genentech's possession required for Xoma to initiate and complete clinical development of Raptiva, including any enabling studies and human clinical trials to the end of Phase II Clinical Trials for psoriasis. Xoma was responsible for all costs incurred in making any process improvements or refinements after Genentech's data and materials transfer.

47. Further, the amended collaboration agreement clearly detailed that Xoma was responsible for all development costs of Raptiva through the successful completion of the Phase II Clinical Trials. Xoma was also responsible for a portion of the development costs incurred in Europe prior to the first regulatory approval permitting sale outside of the United States, up to an undisclosed amount for trial work necessary for European regulatory.

48. Xoma invested and participated in Raptiva marketing events. In its August 13, 2003 quarterly SEC filings, Xoma reported (two months prior to FDA approval of Raptiva) that marketing, general and administrative expenses for the three months ended June 30, 2003 increased to $4.7 million, or an increase of 24%, from the prior year. "The most significant component of this increase was pre-launch activities for Raptiva. Pre-launch marketing expenses for Raptiva are expected to continue at similar or higher levels until the product launch date." In

November 2004, one year after Raptiva's launch into U.S. markets, Xoma reported, "We have spent, and we expect to continue to spend substantial funds in connection with, (among other things), sales and marketing of Raptiva."

49. Under the terms of the amended collaboration agreement, Xoma received 25% of U.S. operating profits from Raptiva in the United States, and Genentech agreed to loan Xoma $80 million to continue the co-development of Raptiva. In addition, Xoma granted Genentech a security interest in Xoma's profit share on Raptiva as collateral against any unpaid past due amounts of the loans. Xoma was granted a co-exclusive license from Genentech for the purpose of using, selling, having sold and offering for sale Raptiva in the United States. The consolidated accounting of operations for the Raptiva collaboration in the United States was referred to as "GenXoma". A five year long range plan for GenXoma was established on a yearly basis under the direction of the JSC and submitted to Genentech and Xoma. Operation of GenXoma was deemed commenced on the date the parties began to share development costs for the Raptiva Phase III Clinical Trials which occurred on or about May 4, 1999.

50. In 2003, Xoma reported Raptiva as one of only three products it had in development. Xoma went on to state "whether [Xoma] can achieve profitability will be highly dependent on sales and expense levels from Raptiva, which [Xoma] has been developing under a collaboration agreement with Genentech..... Xoma will share in the ultimate profits and losses from those sales."

51. On May 15, 2003, Xoma recorded a net quarterly loss of $13 million due in part to increased research and development fees related to Raptiva. The success of Xoma was critically

tied to the success of Raptiva. The sooner Raptiva received FDA approval, the sooner Xoma would show a profit to their institutional investors and individual shareholders.

52. In May 2003, Defendants halted a clinical study developing Raptiva for the treatment of rheumatoid arthritis. An evaluation of the trial outcomes determined that Raptiva did not result in any noticeable clinical benefit in the patients receiving the drug. The results were disappointing for Defendants' strategic visions of competing with the new biologic rheumatoid arthritis drugs two of which, Amgen's Enbrel and Johnson & Johnson's Remicade, had total sales of approximately $2 billion in 2002. One year later, Defendants announced Raptiva failed to show a significant benefit in patients suffering from psoriatic arthritis.

53. In August 2003, Xoma and Genentech reported that the FDA's Dermatologic and Ophthalmic Drug Advisory Committee would review their Biologics License Application (BLA).

54. The Raptiva BLA consisted of information, data, testing, design formulation, and the clinical studies of Raptiva conducted by both Xoma and Genentech.

55. FDA approval of the Raptiva Biologics License Application was based in part on the clinical studies data involving *Xoma manufactured Raptiva* as summarized in the table below.

56. At the time of the application, Defendants submitted thirteen Raptiva clinical trials to the FDA. Of the thirteen trials, more than half were Xoma-conducted with Xoma manufactured Raptiva. Only Xoma conducted all three clinical trial phases, and Xoma carried out the single, critical Phase II trial (human studies designed to evaluate the safety, dose ranging and efficacy of a pharmaceutical) submitted in the biologics application. Moreover, Xoma-manufactured Raptiva accounted for approximately 73% of the "long-term" exposure data submitted to the

FDA (904 subjects – studies ACD 2058/gACD2059g). Genentech-manufactured Raptiva accounted for approximately 27% (339 subjects- ACD2243) of the "long-term" data submitted.

57. Xoma clinical trial data was utilized by Defendants and the FDA to support the warnings, precautions and adverse reaction information in the Raptiva package inserts (warning labels) and patient package inserts.

58. Xoma clinical trial data was incorporated into the marketed Raptiva label and package inserts and was relied upon by Plaintiff and his physicians.

59. On September 9, 2003, the FDA Advisory Committee recommended approval of Raptiva. Xoma shares rose more than 12 percent on the news. Its shares had doubled in the two preceding months in anticipation of Raptiva approval due to Defendants' well-orchestrated, pre-approval publicity campaign that focused on messaging Raptiva efficacy and safety record to Wall Street, dermatologic institutions (such as the American Academy of Dermatology), and academics and universities with renowned dermatology departments/clinics. Genentech shares hit a 52-week high.

60. On September 24, 2003, two weeks after the FDA Advisory Committee recommended approval, Xoma sold 9,000,000 common shares and received approximately $67.2 million in net proceeds.

61. On October 23, 2003, the FDA approved the BLA for Raptiva. At the time of approval, a total of 2,762 patients had been treated with Raptiva. Of those, 2,762 patients, 2,400 had been treated for three months, 904 for six months, and only 218 for one year or more. While the panel approved Raptiva, several members raised concerns about long-term and interrupted use of the

product.

62. Despite these safety concerns, the danger of prolonged or interrupted immunosuppression was ignored by Defendants and Raptiva was launched on November 17, 2003.

D. *XOMA AND GENETECH'S CONCEALMENT OF RAPTIVA'S SERIOUS HEALTH RISK*

i) Rebound Effect Leads to False Promotion of Raptiva as Safe for Continuous Long-Term Use

63. Defendants had originally planned for Raptiva to be a 12-week course of treatment (similar to the competitor Biogen's psoriasis biologic, Amevive). In development, however, Raptiva, was plagued with numerous reports of patients having severe "rebound effects" who ceased using the biologic. Raptiva worked to clear up the skin lesions of psoriasis, but once a patient stopped taking the drug, the disease came back, sometimes in a more aggressive form than a patient's original baseline or pre-Raptiva treatment status. The rebounds (both on and off drug) occurred at new sites on the body where patients had never experienced psoriasis before; they were not flare-ups of existing psoriasis. In several patients who discontinued Raptiva, their plaque psoriasis turned debilitating; some even required hospitalization.

64. Defendants knew the clinical trial data suggested that patients who stopped taking Raptiva relapsed and therefore it was apparent to Defendants that there was a need to remain on the drug for long periods of time, if not continuously for the rest of their lives because psoriasis is a chronic incurable disease. Defendants also knew that long-term immunosuppression increases the likelihood of serious life-threatening, infections (encephalitis, meningitis, PML), neurological complications, lymphomas, malignancies, and possibly death.

65. Nevertheless, Defendants, with a paucity of data to support their claims, made a strategic business decision to promote and market Raptiva as safe for "continuous treatment"

66. On September 9, 2003, Defendants made multiple material misrepresentations and omissions to the Dermatologic and Ophthalmic Drugs Advisory Committee of the FDA, falsely and deceptively reporting that Raptiva was safe for continuous usage:

> Extended therapy with Raptiva provided increased clinical efficacy with no adverse events. Overall, there were few serious adverse events associated with Raptiva therapy, no evidence of organ toxicity, and no evidence of increased malignancies or infections.....Raptiva provides significant new, safe, and efficacious alternative for patients with severe plaque psoriasis.
>
> "When the program began we did not know whether Raptiva would be best used intermittently or continuously, and during the course of these trials, it became clear that Raptiva is really best used continuously.... Raptiva was well tolerated and safe for continuous use" *Michelle Rohrer, Genentech Director of Regulatory Affairs*
>
> "Regarding continuous treatment, in contrast to loss of efficacy when Raptiva is discontinued; the efficacy of Raptiva improves with continuous treatment past 12 weeks. *Lee Kaiser, Genentech Director of Clinical Biostatistics*
>
> "....Raptiva is a very safe and well-tolerated drug..... Raptiva's safety profile over the extended treatment period appears as favorable as its safety profile over the short period." ".....many immunosuppressant drugs have the potential to cause increased risk of malignancies and infections. Raptiva is an immunosuppressant agent...The rates of infections are serious adverse events appear to remain constant over time. So based on this data, Raptiva's safety profile is maintained with extended treatment." *Richard Chin, Genentech Director of Clinical Research for the Specialty Biotherapeutics*
>
> "Overall, there is a favorable adverse event profile, particularly with respect to infection and malignancy." *Charles Johnson, Genentech Senior Director, Clinical Development Group for Specialty Biotherapeutics*

67. At all times material, Defendants provided no information regarding duration of treatment (continuous, long-term, indefinite use) in their product labeling for Raptiva and/or in Defendants' marketing materials. As a direct and proximate result of the failures of Defendants to adequately disclose the risk of long-term continuous immunosuppression to prescribing physicians in the United States, including Plaintiff's physicians and Plaintiff, physicians prescribed and over-prescribed Raptiva to patients, and both prescribing physicians and the consume public, including plaintiff, were grossly under-informed regarding the risk of serious health effects.

ii) No Required Diagnostic Monitoring to Conceal Serious Health Risks

68. Further, Defendants, despite their knowledge of the serious health risks associated with the continuous immunosuppressive therapy with Raptiva, failed to implement a patient monitoring program in order to provide early detection of serious life-threatening infections (encephalitis, meningitis, PML), neurological complications, lymphomas, and malignancies – all associated with immunosuppressant therapies. Defendants made a strategic business decision not to require baseline blood work or physical exams prior to commencing Raptiva, not to institute a required weekly, monthly, or quarterly health assessment during long-term continuous usage of Raptiva. Raptiva patients were receiving a novel immunosuppressant agent with no required ongoing physician visits, physical exams, x-rays or regular blood or laboratory diagnostic assessments to monitor for serious health risks during Raptiva usage or prior to prescription renewal.

69. At all times material, Defendants falsely and deceptively explained away the need for monitoring requirement by indicating it "might not be good for patients" as Susan Desmond-

Hellmann, Chief Medical Officer and Executive Vice President of Product Development and Product Operation at Genentech stated on September 9, 2003: ".... While the physician may feel better, the real crux of the matter is, is it good for the patient to monitor their platelets monthly, every three months.....when we looked at the data there's not really evidence that that's [monitoring] good for patients and so we'll have to balance what makes you [physicians] feel good and what's good for the patients."

70. Defendants' explanation was pretextual. The real reason for not requiring medical monitoring was twofold: (i) to undermine the reporting by physicians and patients of the adverse health risks associated with Raptiva; and (ii) for strategic marketing purposes, Defendants wanted to distinguish Raptiva as the easier and more convenient alternative to their main competitor, Amevive, which required administration in a physician's office and required monitoring every two weeks. "From a commercial standpoint, we would prefer not to see monitoring on a monthly basis..." Diane L. Parks, Genentech's Vice President of Cardiovascular & Specialty Therapeutics, Marketing & Sales.

71. At all times material, Defendants knew and failed to inform plaintiff, plaintiff's physician and the general public that required monitoring would provide early detection and most likely prevent the very health risks which ultimately led Raptiva to be taken off the market: serious life-threatening infections (encephalitis, meningitis and PML), neurological complications, lymphomas, malignancies and death. Defendants fought for years to keep safety concerns from destroying Raptiva's commercial prospects, thus enabling them to sell Raptiva as a premium psoriasis drug when it was not.

iii) Direct Shipments to Patients Bypasses Physician Detection of Serious Health Risks

72. In order to maximize their profits from the sale of Raptiva and recoup their significant developmental costs, Defendants marketed Raptiva as "safe, effective, convenient, long-term, continuous control."

73. To support their marketing campaign of "convenient, continuous" use, Defendants developed a delivery system utilizing a network of specialty pharmacies in which Raptiva (the biologic must be refrigerated) was delivered overnight directly to the patient's home- thereby bypassing the need for physicians' visits altogether which furthered the concealment of Raptiva's health risks.

74. Plaintiff, Gerald Sylvia received his initial Ratpiva prescription from his dermatologist along with a lesson on how to self-administer the injection. Subsequent refills were sent directly to Gerald's home with only an annual refill request.

iv) False Statements Touting Safety of Long-Term Usage While Ignoring Adverse Event Reports

75. From post-market approval in October 2003 until the time Raptiva was withdrawn from the market in 2009, Defendants repeatedly made false and deceptive statements regarding the safety of Raptiva and, by issuing a relentless series of press releases and publications touting Raptiva's "safety and efficacy" profile while concealing the truth about its serious life-threatening health risks and the adverse event reports associated with Raptiva usage.

76. On October 27, 2003, Defendants issued a joint press release to announce that the FDA

had approved Raptiva. "Raptiva represents Xoma's first product approval and is the culmination of a highly successful collaboration with Genentech," said John L. Castello, Xoma's chairman, president and chief executive officer. "The companies have worked together on a robust clinical program that has demonstrated the safety and efficacy of Raptiva."

77. The next day, Xoma President Castello stated in an interview, "We think it's a tremendously competitively product, both with what's in the market now and what's coming." Mr. Castello said. *"It's got a very good safety profile—we've seen no increase in cancer or organ damage.* It's convenient....Its efficacy looks very good."

78. On November 19, 2003, Defendants issued a joint press release announcing the results of a study to be published in the *New England Journal of Medicine* in which patients who received extended treatments to 24 weeks continued to benefit from the drug. Hal Barron, Genentech's Vice President of Medical Affairs said, "These results clearly illustrate the benefit of continuous therapy with Raptiva and support the efficacy seen in over 3,000 patients treated with Raptiva in clinical trials to date."

79. On February 22, 2005, Genentech presented a three-year study of Raptiva at the American Academy of Dermatology which showed "long-term and sustained clearing in psoriasis patients with minimal side-effects." A same-day press release reported that adverse events in this study were similar to what had been observed in previous 12 week clinical trials of Raptiva: headache, non-specific infection (e.g. common colds), chills, pain, nausea, asthenia (weakness), and fever, all of which diminished after the first 1-2 doses. Further, the press release reported that there *was no evidence of cumulative toxicity or increased malignancy or infection.* A Genentech paid

clinical investigator, Craig Leonardi, M.D., stated in the press release "Raptiva is the first biologic therapy to show sustained benefit for psoriasis patients treated continuously over a three-year period. Given that psoriasis is a chronic disease, as dermatologists we must weigh the efficacy and safety of different treatment options over the long term. It is encouraging to see a consistent safety profile for Raptiva in this three-year open label study."

80. On March 5, 2008, in another press release, Genentech, continued to falsely and deceptively assert through its paid investigator, Dr. Craig Leonardi, that Raptiva was safe for long-term continuous use: "Final results of the first three-year prospective efficacy and safety study of Raptiva was recently published....Raptiva demonstrated sustained safety long-term efficacy and favorable safety profile in this three-year trial. These features make it appropriate for continuous, long-term treatment of plaque psoriasis."

81. These statements were repeated in countless continuing medical education symposiums and complimented by numerous papers in peer-reviewed medical literature by Defendants' employees and paid consultants, all of which attempted to downplay concerns about the adverse long-term continuous use of Raptiva.

82. While touting Raptiva's safety of long-term continuous use, Defendants falsely and deceptively failed to inform plaintiff, his physicians and the public that by March 5, 2008, Defendants had knowledge and receipt of approximately 60 adverse event reports of patient deaths while on Raptiva, and over one hundred adverse event report of serious life-threatening infections leading to hospitalizations.

83. Defendants failed to timely and approximately amend, change, supplement, alter, or

otherwise update the product labeling, package insert, or to otherwise advise physicians, patients, pharmacists, or other health care providers of the increasing number of adverse events reported, specifically the number of serious infections leading to hospitalizations, the number of malignancies and lymphomas and the number of deaths reported, and otherwise omitted such data and information regarding the aforementioned dangers associated with the use of Raptiva in the information shared with the medical community and the consumer public.

84. Despite the increasing number of adverse events reported after FDA approval of Raptiva, Defendants refused to modify or amend the Raptiva label to include a black box warning, the highest level of warning, for increased risk of serious life-threatening infections (encephalitis, meningitis, PML), neurological complications, lymphomas, malignancies and death, and/or require patient monitoring to ensure safe usage of Raptiva and early detection of health risks.

85. In October 2008, after five years on the market, the FDA finally issued a black box warning for Raptiva highlighting the risk of life-threatening neurological complications, bacterial and viral infections, including bacterial sepsis, viral meningitis, invasive fungal disease and other opportunistic infections, as well as the increased risk of cancer. The FDA also included a boxed warning specifically for PML. The FDA had received reports of serious infection leading to hospitalization, and death in patients using Raptiva.

86. In February 2009, the FDA issued a Public Health Advisory concerning three deaths in patients treated with Raptiva. Two involved people with confirmed cases of progressive multifocal leukoencephalopathy. The third death was a person believed to have contracted the brain infection, according to the advisory.

87. On February 20, 2009, the European Medicines Agency recommended to the European Commission the suspension of the marketing for Raptiva. After reviewing a comprehensive benefit-risk re-assessment, the EMEA's Committee for Medicinal Products for Human Use concluded that the benefits of Raptiva no longer outweighed its risks. In the European Union, physicians were advised not to issue *any* new prescriptions for Raptiva.

88. On February 20, 2009, Canada suspended the sales of Raptiva due to safety concerns. On April 8, 2009, after more reports of serious injury Defendants announced a phased withdrawal of Raptiva from United States markets due to safety concerns. On June 8, 2009, Raptiva was removed from U.S. markets. Raptiva is the first drug Genentech withdrew from the market in its 33 year history.

COUNT I
Strict Products Liability

89. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

90. The Defendants manufactured their Raptiva and placed it into the stream of commerce in a defective and unreasonably dangerous condition such that the foreseeable risks exceeded the benefits associated with the design and/or formulation of the product.

91. The Defendants negligently designed, developed, tested, manufactured, inspected, marketed, promoted, advertised, sold and/or distributed the Raptiva which injured the Plaintiff.

92. The Defendants negligently failed to warn, instruct, adequately warn or adequately instruct the Plaintiff or his physician of the dangerous properties of Raptiva.

93. The Defendants negligently marketed and sold Raptiva when they knew, or with reasonable care should have known that Raptiva was unreasonably dangerous, not reasonably safe, and defective in nature and design or in an unreasonably dangerous, not reasonably safe and defective condition, and negligently marketed and sold and/or placed Raptiva in the channels of trade in a manner which Defendants foresaw, or in the exercise of reasonable care ought to have foreseen, would carry Raptiva into contact with persons such as Plaintiff who was unaware of the unreasonably dangerous, not reasonably safe and defective nature and conditions of the devices.

94. Plaintiff was given Raptiva as prescribed by his physician in a manner that the Defendants intended the drug to be used.

95. Defendants' Raptiva was expected to and did reach Plaintiff without substantial change in condition.

96. The Defendants' Raptiva was defective due to inadequate warning and/or inadequate clinical trials, testing and study and inadequate reporting regarding the results.

97. The Defendants' Raptiva was defective due to inadequate post-marketing warning or instruction because, after the Defendants knew or should have known of the risk of injury from their Raptiva, they failed to provide adequate warnings to the medical community and patients, and continued to promote the products as safe and effective.

98. The defective warnings and labeling were substantial factors in bringing about the injuries to the Plaintiff.

99. The Raptiva manufactured, distributed, sold, tested, marketed, advertised and represented defectively by the Defendants, was a substantial factor in bringing about the injuries to the Plaintiff.

100. As the direct and proximate cause of the defective condition of the Raptiva as manufactured and/or supplied by the Defendants, and specifically their failure to warn, and their negligence, carelessness, other wrongdoing and actions described herein, Plaintiff suffered those injuries and damages as described with particularity, above.

WHEREFORE, Plaintiffs, pray for judgment against the Defendants in an amount greater than $75,000, plus costs, and interest, as this Court may find just and equitable.

COUNT II
Negligence

101. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

102. The Defendants were under a duty to exercise reasonable care, and to comply with the existing standards of care, in designing, manufacturing, testing, distributing, marketing, and selling of their product, Raptiva.

103. The Defendants owed a duty of care to the Plaintiff to manufacture and sell non-defective products.

104. Defendants breached their duty of care and failed to exercise the appropriate degree of care in the designing, manufacturing, testing, distributing, marketing, and selling of their Raptiva

products, including the duty to assure that their products did not pose a significantly increased risk of bodily harm and adverse events.

105. In breach of those duties, Defendants failed to exercise the appropriate degree of care and vigilance in the design, formulation, manufacture, sale, testing, quality control, quality assurance, labeling, warning, marketing, and distribution of Raptiva.

106. Despite the fact that Defendants knew or should have known that their Raptiva posed a serious risk of bodily harm and was inherently dangerous, Defendants continued to manufacture and market such products for administration.

107. Defendants knew or should have known that persons such as Plaintiff would suffer injury as a result of Defendants' failure to exercise the highest possible degree of care as described above.

108. Had the Plaintiff not received the Defendants' Raptiva product, he would not have developed meningitis and acute necrosis, and would not have suffered those damages described with particularity, above.

109. As a direct and proximate cause of Defendants' negligence and failure to comply with appropriate standards of care, Plaintiff suffered serious physical injury resulting in the loss of vision, damages and economic loss and Plaintiff will continue to suffer, and economic loss in the future.

WHEREFORE, Plaintiffs, pray for judgment against the Defendants in an amount greater than $75,000, plus costs, and interest, as this Court may find just and equitable.

COUNT III
Breach of Express Warranty

110. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

111. Defendants expressly warranted that their Raptiva were a safe and effective.

112. The Raptiva manufactured and sold by Defendants did not conform to these express representations because one or more of them caused serious injury to the Plaintiff when administered in recommended dosages.

113. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury and economic loss and Plaintiff will continue to suffer such damages, and economic loss in the future.

WHEREFORE, Plaintiffs, pray for judgment against the Defendants in an amount greater than $75,000, plus costs, and interest, as this Court may find just and equitable.

COUNT IV
Breach of Implied Warranty

114. Plaintiffs incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further alleges as follows.

115. At the time Defendants designed, manufactured, marketed, sold, and distributed their Raptiva, Defendants knew of the use for which those products were intended and impliedly warranted the products to be of merchantable quality, safe for such use, and fit for the ordinary purposes for which the products were used.

116. Plaintiff and his physicians reasonably relied upon the skill and judgment of Defendants as to whether Defendants' product was of merchantable quality and safe for its intended use and upon Defendants' implied warranty as to such matters.

117. Contrary to such implied warranty, Defendants' Raptiva were not of merchantable quality or safe for the intended use because the products are unreasonably dangerous as described above.

118. Defendants' breached their implied warranty of merchantability because their Raptiva because of design defect, manufacturing defect, and Defendants' failure to warn users such as Plaintiff and his physicians of the latent dangers in the normal and intended use of the products.

119. As a direct and proximate result of Defendants' breach of warranty, Plaintiff suffered serious physical injury resulting in permanent damages, and economic loss and Plaintiff will continue to suffer damages and economic loss in the future.

WHEREFORE, Plaintiffs, pray for judgment against the Defendants in an amount greater than $75,000, plus costs, and interest, as this Court may find just and equitable.

COUNT V
Fraud/Misrepresentation/Deceit

120. Plaintiff incorporates by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows.

121. Defendants each knowingly and intentionally made material and false and misleading representations to Plaintiff, his physicians and to the public that Raptiva was safe for use and that Defendants' labeling, marketing and promotion fully described all known risks of the product.

122. Defendants' representations were in fact false and deceitful, as Raptiva is not safe for use and its labeling, marketing and promotion did not fully describe all known risks of the product.

123. Defendants had actual knowledge based upon studies, published reports and clinical experience that their Raptiva created an unreasonable risk of serious bodily injury and death to consumers, or should have known such information.

124. Defendants knowingly and intentionally omitted this information in their product labeling marketing, and promotion and instead, labeled, promoted and marketed their product as safe for use in order to avoid monetary losses and in order to sustain profits in its sales to consumers.

125. When Defendants made these representations that their Raptiva was safe for use, they knowingly and intentionally concealed and withheld from Plaintiff, his physicians and the public the true facts that such solutions were not safe for use in consumers with renal insufficiency.

126. Defendants had a duty to disclose to Plaintiff, his physicians and the public that Raptiva was not safe and they had superior knowledge of these facts that were material to Plaintiff and his physicians' decision to use Raptiva.

127. Plaintiff and his physicians reasonably and justifiably relied on the Defendants' concealment of the true facts and reasonably and justifiably relied upon Defendants' representations to Plaintiff and/or his health care providers that Raptiva was safe for human consumption and/or use and that Defendants' labeling, marketing and promotion fully described all known risks of the product.

128. Had Plaintiff and his physicians known of Defendants' concealment of the true facts that Raptiva was not safe for human use, Plaintiff would not have been administered Raptiva, and

would not have developed meningitis and acute retinal necrosis, or suffered those injuries as described with particularity, herein.

129. As a direct and proximate result of Defendants' misrepresentations and concealment, which was known to the Defendants, and upon which they intended him to rely, and upon which he did rely, Plaintiff administered Raptiva and Plaintiff has suffered serious permanent physical injury, harm, damages and economic loss and will continue to suffer such harm, damages and economic loss in the future.

WHEREFORE, Plaintiffs, pray for judgment against the Defendants in an amount greater than $75,000, plus costs, and interest, as this Court may find just and equitable.

COUNT VII
Loss of Consortium

130. Plaintiffs, incorporate by reference, as if fully set forth herein, each and every allegation set forth in the preceding paragraphs and further allege as follows

131. That at all times relevant hereto, Plaintiff, Cynthia Rose was the wife of Plaintiff Gerald Sylvia.

132. As a direct and proximate result of the conduct of Defendants described herein, Plaintiff Cynthia Rose has been deprived of the comfort, society, aid, services, consortium, and support of her husband, and has otherwise suffered loss.

WHEREFORE, Plaintiffs, pray for judgment against the Defendants in an amount greater than $75,000, plus costs, and interest, as this Court may find just and equitable.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a jury trial on all issues presented in this action.

Respectfully submitted,

/s/ Bruce A. Bierhans
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